



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

August 7, 2007

**MEMORANDUM**

**Subject:** Efficacy Review for Axen50;  
EPA Reg. No. 72977-U; DP Barcode: D338328

**From:** Marcie Tidd, Microbiologist  
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**Thru:** Tajah Blackburn, Acting Team Leader  
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**To:** Marshall Swindell PM 33 / Karen Leavy  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**Applicant:** ETI H20  
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**Formulation from the Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Silver.....	0.005%
Citric Acid.....	5.000%
<u>Other Ingredients</u> .....	<u>94.995%*</u>
Total.....	100.000%

\*Incorrectly recorded as 100.000% on the proposed label.

## I. BACKGROUND

The product, Axen50, is a new product (Reg. No. 72977-U) intended for use as a food contact sanitizing solution. This is a new food use for the active ingredient Silver, and a tolerance petition is currently in-house with RASSB for review. The applicant has submitted data to support food contact sanitization claims. The submitted study was conducted by ATS Labs, located at 1285 Corporate Center Drive, Suite 100 in Eagan, MN.

The data package included a letter from the applicant's representative to the Agency (dated January 9, 2007), the Confidential Statement of Formula, the Data Matrix, the proposed label (dated January 8, 2007), and one study (MRID 470398-04) with statements of No Data Confidentiality and Good Laboratory Practice. An additional, revised label was sent in at the Agency's request, removing a claim for *Escherichia coli* O157:H7 from the label. The revised label is dated March 29, 2007.

## II. USE DIRECTIONS

The product is intended for use as a food contact surface sanitizer in household and institutional food establishments such as restaurants, bars, cafeterias, food storage areas, coffee shops, delis, food processing plants, dairy farms, poultry and turkey farms, and cruise ships. The product is to be used on hard, non-porous surfaces such as dishes, glassware, silverware, cooking utensils, non-porous cutting boards, coolers, refrigerator bins, ice machines, picnic tables, drinking fountains, kitchen equipment, and citrus processing equipment. The proposed label did not list specific material types the product is to be used on.

The proposed label lists the following use directions for sanitizing hard, non-porous food contact surfaces. Scrape, flush or presoak articles to remove gross food particles and soil. Thoroughly wash articles in an appropriate detergent or cleaner. Rinse articles thoroughly with potable water. Apply product to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, sprayer or by immersion. For spray applications, spray product 6 to 8 inches from surface using a trigger sprayer or coarse pump. Surfaces should remain wet for 1 minute followed by adequate draining and air drying.

## III. AGENCY STANDARDS FOR PROPOSED CLAIMS

### **Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces: Additional Microorganisms)**

Effectiveness against additional bacteria other than *Escherichia coli* and *Staphylococcus aureus* required for sanitizing rinses on previously cleaned, food contact surfaces can be supported by confirmatory testing: 2 product samples representing 2 different product lots against the organism. These are the same requirements for disinfectants against additional microorganisms. Performance requirements call for a bacterial reduction of at least 99.999% in the number of organisms within 30 seconds. In addition, the AOAC test method states that counts on the numbers control should fall between 75 and 125 x 10<sup>6</sup> CFU/mL for percent reductions to be considered valid. Results must be presented

as the actual count and percentage reduction over the control. The minimum concentration of the test product which provides the above results is the minimum effective concentration. If hard water effectiveness claims are made, testing must be done at the hard water tolerance claimed. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. The above Agency standards are presented in DIS/TSS-4 and 17 and in the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants method.

#### IV. SUMMARY OF SUBMITTED STUDY

**MRID 470398-04 “Germicidal and Detergent Sanitizing Action of Disinfectants” for Axen50 by Becky Lien. Study conducted by ATS Labs, Project Number A04487. Study completed November 28, 2006.**

This study was conducted against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) following ATS protocol number IMS01100606 (copy not provided). Three lots (Lot Nos. 2006.29.001, 2006.270.001, and 2006.178.001) of the product were tested, one of which (Lot 2006.178.001) was at least 60 days old at the time of testing. The product was received ready-to-use. 1.0 mL aliquots of each test organism (standardized to a 4.0 McFarland Standard) were added to flasks containing 99 mL sterile PBDW at 25.0C and held in contact for 30 seconds. Following exposure, 1.0 mL of the exposed culture was removed from each flask and added to 9 mL of Lethen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.05% Catalase to neutralize. After mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized test solution were transferred into individual sterile Petri dishes. Approximately 15-20 mL of Trypton Glucose Extract Agar (TGEA) was added to each plate. Plates were swirled to mix, then cooled and inverted. Plates were incubated for 44 hours at 35-37C before enumeration of the survivors. Plates were stored at 2-8C for two days prior to reading. Following incubation and storage, plates were visually examined for growth. Controls included those for purity, sterility, viability, numbers control, and neutralization confirmation.

#### V. RESULTS

MRID	Organism	Microbes Initially Present (CFU/mL)	Results: Average Number Surviving (CFU/mL)			Percent Reduction
			Lot 269.001	Lot 270.001	Lot 178.001	
470398-04	<i>Escherichia coli</i>	$1.39 \times 10^8$	$<1 \times 10^2$	$<1 \times 10^2$	$<1 \times 10^2$	>99.999%
	<i>Staphylococcus aureus</i>	$9 \times 10^7$	$<1 \times 10^2$	$<1 \times 10^2$	$<1 \times 10^2$	>99.999%

#### VI. CONCLUSIONS

1. The submitted data support the use of the product, Axen50, as a food contact surface sanitizer against *Escherichia coli* and *Staphylococcus aureus* on hard, non porous surfaces at full strength with a contact time of one minute (tested at 30 seconds) at room

temperature. Testing demonstrated at least a 5 log reduction for 3 lots of each organism, one of which was at least 60 days old at the time of testing. Controls were acceptable for a valid test.

## VII. RECOMMENDATIONS

1. The proposed label claims that the product, Axen50, is an effective sanitizer for use on food contact surfaces in 60 seconds (undiluted) against 99.999% of bacteria (*E. coli* and *S. aureus*). These claims are acceptable.\*

\*These claims are acceptable provided that RASSB finds the tolerance petition for silver to be acceptable for food contact surface use at the use concentration of this product.

2. The following changes need to be made to the proposed label (3/29/07 Draft).
  - a. On page 1, change the percentage of "Other Ingredients" from 100.000% to 94.995% and add an additional line below which reads, "Total....100.000%."
  - b. On page 3 (first bullet), remove the following use sites: dairy farms, hog farms, equine farms, and poultry and turkey farms. These are not approved as food-contact use sites for a sanitizer product. Only disinfectant products, with the appropriate farm and poultry premise language, may have farm sites on their label.  
  
Similarly, the applicant must also remove "Poultry and/or Turkey Farms" and "Equine Farms" from page 4 of the label.
  - c. On page 3, remove "toy factories" from the list of use areas for the product. This is not a food contact surface use.
  - d. On page 4, the applicant needs to remove "Pacifiers" from the types of surfaces section. [Note to PM: Confer with tox to determine if this is an appropriate route of exposure]
  - e. On page 6 (the residential use box), the applicant must include instructions for the thorough pre-cleaning of the surfaces/objects with detergent or compatible cleaner, followed by a potable water rinse prior to application of the sanitizing solution.
  - f. The applicant must include a listing of material types for use (i.e. stainless steel, plastic, etc.).